7 STATEMENT AND SUMMARY INFORMATION

INTRODUCTION

As outlined in Chapter 2 of this manual, a premarket notification 510(k) submission needs to include:

- a Truthful and Accurate statement,
- an Indications for Use statement, and
- a 510(K) Summary **or** Statement.

This information helps assure the accuracy of submissions, overtly states the indications for use of the device, speeds the processing of the submission, and supports the fulfillment of requests by the public for information under the Freedom of Information (FOI) Act. These are described below.

TRUTHFUL AND ACCURATE STATEMENT AND FORMAT

All 510(k) submitters must include a statement certifying that all information contained in the 510(k) submission is truthful and accurate and that no material fact has been omitted.

The truthful and accurate statement ***must*** be on a separate page and ***must*** be identified in the table of contents.

A sample is provided on the next page.

Sample

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as (
_____)
The position held in the company

of (
_____),
Manufacturer's Name

I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
Signature

_____
Typed Name

_____
Dated

_____
* Premarket Notification 510(k) Number

The statement *must* be signed by a responsible person of the company required to submit the premarket notification — ***not*** a consultant for the submitter.

* For a new submission, do ***not*** fill in the 510(k) number. The Food and Drug Administration will fill in this blank with your 510(k) number when the number is assigned.

INDICATIONS FOR USE STATEMENT AND SAMPLE FORMAT

Each 510(k) submission must include an "Indications for Use" page that contains the applicant's name, name of the device and the indications for use of the device. For medical gloves, the indication for use is the same as the intended use. The Indications for Use page should contain the 510(k) number for the submission when the 510(k) number is known (for example, when submitting additional information requested by FDA). For a new submission, however, you will not know the number and will not be able to include it. The Indications for Use statement should be located in the front part of your 510(k) submission.. An example of an optional format is on the next page which you may use. It may be completed by using one of the following statements or equivalent text.

The following statements are from the proposed reclassification of medical gloves.

1. For basic **powdered** examination gloves, you may state: *A powdered patient examination glove is a disposable device made of natural rubber latex or synthetic material that bears powder to facilitate donning and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.*

2. For basic **powder-free** examination gloves, you may state: *A powder-free patient examination glove is a disposable device made of natural rubber latex or synthetic material that may bear a trace amount of glove powder and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.*

3. For basic **powdered** surgeon's gloves, you may state: *A powdered surgeon's glove is a disposable device made of natural rubber latex or synthetic material that bears powder to facilitate donning, and it is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.*

4. For basic **powder-free** surgeon's gloves, you may state: *A powder-free surgeon's glove is a disposable device made of natural rubber latex or synthetic material that may bear a trace amount of glove powder and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.*

You may use equivalent text that correctly describes the indications for use of your gloves. For a special purpose glove, you must include additional text in the Indications for Use statement that covers the additional function of the glove as claimed in your labeling. The FDA, CDRH, Office of Device Evaluation (ODE) will review the contents of your entire 510(k) submission to determine if the submission supports your Indications for Use statement. Therefore, the information, data and labeling claims in the entire 510(k) submission must support and agree with the Indications for Use statement. The Indications for Use statement will be attached by ODE to the substantial equivalence (SE) letter which ODE will send to the submitter to define for what use the glove was cleared for marketing.

Sample Format

INDICATIONS FOR USE

Applicant's Name: _____

510(k) Number (if known): *_____

Device Name: _____

Indications For Use:

***For new submissions, do **NOT** fill in the 510(k) number.

510(k) SUMMARY OR STATEMENT

Section 513(i) of the FD&C Act requires that a person submitting a premarket notification [510(k)] to the FDA **must** include either:

1. a summary of the 510(k) safety and effectiveness information upon which the substantial equivalence claim is based; or

2. a statement that the 510(k) safety and effectiveness information supporting the claim of substantial equivalence will be made available by your company to any person within 30 days of a written request.

Use of Summaries and Statements

Summaries are used by FDA to fulfill requests made under the Freedom of Information (FOI) Act. Statements are used to make arrangements for the applicant or certifier to respond to requests.

Who Responds to Requests for 510(k) Information

In instances where a manufacturer or other applicant provides a summary with the 510(k) submission to satisfy the conditions in (1) above, written requests by individuals for copies of the 510(k) summary will be furnished by the FDA through the FOI process after determining that the device is substantially equivalent to another device.

If a manufacturer or other person submitting a 510(k) chooses to provide a statement to satisfy the conditions in (2) above, written requests by any individual for a copy of the 510(k), excluding patient identifiers and trade secret and confidential commercial information, must be fulfilled by the statement certifier within 30 days of receipt of the request. On a monthly basis the FDA publishes the list of names of certifiers of premarket notification submissions for which substantial equivalence determinations have been made [§807.93(b)]. A submitter of a 510(k) may not charge requesters for compiling and disseminating this data.

The choice between the above summary and statement should be made before the 510(k) is submitted. However, submitters may elect to change their choice between a summary or statement before the substantial equivalence determination is reached. After this determination is made, submitters cannot change their choice of a summary or statement.

REQUIREMENTS FOR A 510(k) SUMMARY

If you choose to meet the conditions for a **summary**, then a summary **must** be submitted with your 510(k) application and clearly marked as such in order for the FDA to **begin** its review of a 510(k) submission. A complete and correct summary as described below must be submitted in order for FDA to **complete** its review of a 510(k) submission. As required by §807.92(a), FDA will accept summaries and amendments thereto until FDA issues a determination of substantial equivalence.

Please make a copy of the following to use as a checklist and check off each item to **make sure** your summary is adequate and complete.

1 [ ] The summary is a separate section of the submission, beginning on a new page and ending on a page not shared with any other part of the premarket notification submission, and is clearly identified as "510(k) SUMMARY" as required by §807.92(c).

2 [ ] The summary contains on the first page, preferably on your letterhead paper, the submitter's name, address, phone and Fax numbers, name of contact person, and date the summary was prepared [§807.92(a)(1)].

3 [ ] The summary includes the name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known [§807.92(a)(2)].

Examples:

- Trade name - DR@GON® LATEX EXAMINATION GLOVES
- Common name - exam gloves
- Classification name - patient examination glove, powdered (per proposed 21 CFR 880.6250), or
  - patient examination gloves, powder-free (per proposed §880.6251)

4 [ ] The summary identifies the legally marketed device to which your company is claiming equivalence [§807.92(a)(3)].

Example: Class I* powdered latex patient examination glove 80LYY, powdered with absorbable dusting powder, that meets all of the requirements of ASTM standard D 3578-95.
* [Class II if proposal becomes a rule.]

5 [ ] The summary includes a description of the device [§807.92(a)(4)].

For gloves, simply repeat the information in step 4 above and describe any variations. For special purpose gloves describe the special features. For example, for orthopedic gloves, also add as appropriate: The gloves are ## mm thick (and have technical features) to reduce damage from contacting bone, teeth or instruments.

6 [ ] The summary describes the intended use of the device [§807.92(a)(5)].

For gloves, you may select indications for use text from the appropriate one of the 4 numbered proposed paragraphs on preceding page 7-3 that matches your gloves, or equivalent text. This text should agree with the text in your "Indications For Use" statement.

7 [ ] Per §807.92(a)(6), the 510(k) summary contains a summary of the technological characteristics of your device compared to the predicate device. If your device has different technological characteristics from the predicate device, the 510(k) summary contains a summary of how the

technological characteristics of your device compare to a legally marketed device to which you are claiming equivalence.

For gloves, include a brief table of: the measured parameters of your finished gloves compared to ASTM or equivalent standards; data that shows compliance with FDA biocompatibility, pinhole, powder-free and other requirements and recommendations; and any other parameter for which you have a labeling claim.

8 [ ] If the determination of substantial equivalence is also based on an assessment of performance data, the summary includes a brief discussion of the nonclinical tests and how their results support a determination of substantial equivalence [§807.92(b)(1)].

Example - The performance test data is the same as for §807.92(a)(6) mentioned immediately above.

9 [ ] If the determination of substantial equivalence is also based on an assessment of performance data, the summary includes a brief discussion of clinical tests and how their results support a determination of substantial equivalence [§807.92(b)(2)].

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

10 [ ] Per §807.92(b)(3), the summary includes the conclusions drawn from the nonclinical and clinical tests in (b)(1) and (b)(2). [See steps 8 and 9 above.]

For gloves, state that your gloves:

- meet or exceed the ASTM standard or equivalent standard; and
- meet your labeling claims and pinhole AQL as shown by the data in (a)(6). [See step 7 above.]

11 [ ] Per §807.92(d), the summary includes any other standards, special controls, labeling, or regulatory information reasonably deemed necessary by the FDA. Such additional information requested by FDA during review of the submission may include additional safety and effectiveness information and FDA may request that you update your summary.

Please make sure you have included all of the information listed in steps 1 to 11 above and verify that the following criteria have been met.

- The summary includes only information that is also covered in the body of the 510(k).
- The summary does not contain any puffery or unsubstantiated labeling claims.
- The summary does not contain any raw data, i.e., contains only summary data.
- The summary does not contain any trade secret or confidential commercial information.
- The summary does **not** contain any patient identification information.

If you use a summary, writing and reviewing the summary are the last steps in preparing your submission.

After completing your 510(k) according to the format in chapter 8 for examination gloves or chapter 9 for surgeon's gloves, *make two copies of your complete 510(k) including your signed summary. Keep one copy for your records. Submit the complete original 510(k), including the summary, and a complete copy of the 510(k), including the summary, to the FDA.*

REQUIREMENTS FOR A 510(k) STATEMENT AND SAMPLE FORMAT

For persons who choose to submit a statement with their 510(k) to the FDA, the specific statement shown below **must** be submitted with the 510(k) in order for FDA to **begin** the review process. The statement should be on a **separate letterhead page**, clearly identified as "510(k) statement," signed by the certifier — **not** a consultant to the 510(k) submitter, and must include the specific language beginning with "I certify ...," shown in the following sample as required by 21 CFR 807.93:

[your company letterhead]
[your address, phone and FAX numbers]

510(K) STATEMENT

"I certify that in my capacity as (*the position held in company by the person required to submit the premarket notification, preferably the official correspondent*) of (*manufacturer's name*), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61."

Signature of Certifier

Typed Name

Date

Premarket Notification [510(k)] Number)*

* For a new submission, do ***not*** fill in the 510(k) number. The FDA will fill in this section with your 510(k) number when the number is assigned.

If you use a statement, writing and reviewing the statement are the last steps in preparing your submission.

After completing your 510(k) according to the format in chapter 8 for examination gloves or chapter 9 for surgeon's gloves, make two copies of your complete 510(k) including your signed statement. Keep one copy for your records. Submit the complete original 510(k), including the statement, and a complete copy of the 510(k), including the statement, to the FDA.